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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,014	10/21/2003	Scott E. Boatman	8627-325	9347

7590 04/07/2004

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EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/691,014

Applicant(s)

BOATMAN, SCOTT E.

Examiner

Jackson J Suzette

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/21/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3-5, 7, 11, 14, 19, and 21-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Abraham et al. 2003/0171824. Abraham et al. discloses the invention as claimed comprising: A cannula ([0017] formed from at least a first layer and a second layer [0018 ...*two or more layers...*], wherein the first layer and second layer each are made of different non-synthetic [0011 "...or from different collagen materials...], natural tissue without the presence of a synthetic support structure; wherein the cannula comprises an opening extending through a wall defined by the first layer and second layer; made of small intestine submucosa [0014-0016]; including growth factors [0018 pg. 3 *growth factors*]. It is inherent that first, second, third or more layers can be provided by the disclosure of Abraham et al.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3738

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 6, 8-9, 12, 15, 20, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. in view of Schaldach et al. Abraham has been disclosed above however Abraham does not teach the use of cartilage. Schaldach et al. teaches a tubular conduit for vascular use manufactured from cartilage (see [0012; 0018; 0021; 0042; 0053; 0060; 0068]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Abraham and incorporate a layer of cartilage (by any alternating layer design) because Abraham discloses in section [0011] that two or more different types of material having collagen may be utilized for the layers and that they may be boned together and Abraham also discloses that the material may be layered with other materials to form a stent [0019].

5. Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. in view of Yang 6,613,082. Abraham et al. has been disclosed above, however Abraham does not specify the use of Paclitaxel. Yang teaches a stent graft with a protein matrix that utilizes Paclitaxel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Paclitaxel in the invention of Abraham et al. because it is well known that Paclitaxel is utilized to treat the implanted area of the vessel.

Art Unit: 3738

6. Claims 9, 13, 18, 30 and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham in view of Schaldach et al. and further in view of Sabolinski 2004/0002772.

Abraham et al. and Schaldach et al. have been disclosed above and while Abraham does teach openings/perforating the tissues [0012] they do not teach laser cutting of openings into the structure. Sabolinski teaches tubular bi or tri-layered implants made from small intestine material ([0011]) that have perforations/fenestrations/holes formed utilizing a laser [0024].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the inventions of Abraham et al. and Schaldach et al. and utilize a laser to form holes and or opening in the tubular structure in order to let surround tissue to become incorporated with the device in order to secure it into the vessel or organ.

### *Conclusion*

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cook et al. 6,206,931 ; Yang 2002/0183857 ; Abraham et al. 2003/016088 ; and Carr, Jr. et al. 2003/0158607; Huckel et al. 2004/0010320 all show related material.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

Art Unit: 3738

9. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J. Jackson

02 April 2004